

JUL 17 2001

K011456

May 10, 2001

Delta Plus for RGP

## SUMMARY

### DELTA PLUS MULTIACTION SOLUTION

The Delta Plus Multiaction Solution is a solution intended to be used for cleaning, rinsing, disinfecting, storing and conditioning of rigid gas permeable contact lenses.

The Delta Plus Multiaction Solution is identical to that cleared in K974485, and this document provides the test results to confirm its safety and efficacy in cleaning, rinsing, disinfecting, storing and conditioning of rigid gas permeable contact lenses. Contained in this document are the viscosity measurements, the wetting angle of lenses before and after 30 cycles of simulated use, lens parameters before and after 30 cycles of simulated use, and the draft labeling. All other information is contained in K974485.

NOTE TO REVIEWER: THE DELTA PLUS MULTIACTION SOLUTION FOR RIGID GAS PERMEABLE LENSES IS IDENTICAL TO ALL-IN-ONE LIGHT MULTIPURPOSE SOLUTION FOR SOFT (HYDROPHILIC) CONTACT LENSES. TEST REPORTS MAY USE THE ALL-IN-ONE NAME, AS THE DELTA PLUS IS A NEW NAME BEING USED FOR THE RGP PRODUCT.

#### I. Chemistry

All details relating to the chemistry of the solution are contained in K974485. The solution characteristics are the same as in K974485. Additional parameters of viscosity and wetting angle were measured, as required for conditioning solutions for rigid gas permeable lenses.

The viscosity of the solution is 3.5 centipoise (see attached report Job 00608, Gaynes Labs, Inc.)

The wetting angles before and after 30 cycles of simulated use were measured with both silicon acrylate and fluorosilicone acrylate lenses, as tabled below (see attached report *Determination of Lens Wettability by Contact Angle Measurement*, Aston University).

	Initial	After 30 cycles
Silicon Acrylate	82°±4	78°±3
Fluorosilicone acrylate	81°±2	72°±3

The use of conditioning solution increased the wettability of both silicon acrylate and fluorosilicone acrylate lenses, although the change in the silicon acrylate lenses is insignificant.

Solution compatibility was determined by cycling silicon acrylate and fluorosilicone acrylate lenses for 30 cycles of simulated use with Optimum Cleaner and Delta Plus Multiaction Solution. No significant differences were seen in lens parameters (diameter, base curve, power) after the 30 cycles of simulated use. (see Custom Hydrophilics Report A00-02, attached)

## II. Toxicology

The toxicological testing of the solution is contained in K974485.

## III. Microbiology

The microbiological testing of the solution is contained in K974485.

## IV. Clinical Studies

All clinical data is contained in K974485.

## V. Substantial Equivalence

The solution is identical to Sauflon Multipurpose Solution for Soft (hydrophilic) Contact Lenses. K974485.

## VI. Manufacturing

Manufacturing is identical to that in K974485 and addended file (see attached Note to File, 2/14/00).

## VII. Shelf Life

The shelf life study protocol is attached.



JUL 17 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Sauflon Pharmaceuticals, LTD.  
c/o John M. Szabocsik, Ph.D  
Official Correspondent  
203 N. Wabash Avenue  
Suite 1200  
Chicago, IL 60601

Re: K011456  
Trade Name: Delta Plus Multiaction Solution for Rigid Gas Permeable Contact Lenses  
Regulation Number: 21 CFR 886.5928  
Regulatory Class: Class II  
Product Code: MRC  
Dated: May 10, 2001  
Received: May 11, 2001

Dear Dr. Szabocsik:

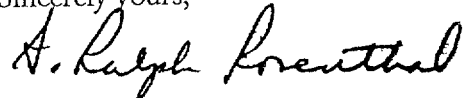
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "A. Ralph Rosenthal". The signature is written in a cursive, flowing style.

A. Ralph Rosenthal, M.D.  
Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

510(k) NUMBER (IF KNOWN) K011456

DEVICE NAME DELTA PLUS MULTIACTION SOLUTION

INDICATIONS FOR USE

The DELTA PLUS MULTIACTION SOLUTION is indicated for use in daily cleaning, rinsing, chemical (not heat) disinfecting, storing and conditioning of rigid gas permeable contact lenses as recommended by your eye care practitioner.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR Over-The-Counter-Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96) Daniel W. C. Brown, Ph.D.

(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K011456